Leila Narvid, Bar No. 229402
ln@paynefears.com
Matthew C. Lewis, Bar No. 274758
mcl@paynefears.com
PAYNE & FEARS LLP
235 Pine Street, Suite 1175
San Francisco, California 94104
Telephone: (415) 738-6850
Facsimile: (415) 738-6855

Daniel F. Fears, State Bar No. 110573
dff@paynefears.com
Andrew K. Haeffele, State Bar No. 258992
akh@paynefears.com
PAYNE & FEARS LLP
4 Park Plaza, Suite 1100
Irvine, California 92614
Telephone: (949) 851-1100
Facsimile: (949) 851-1212

Attorneys for Defendants CVS HEALTH CORPORATION; CVS PHARMACY, INC.; GARFIELD BEACH CVS, LLC; and CVS RX SERVICES, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA, OAKLAND DIVISION

RYAN HYAMS, an individual,

Plaintiff,

vs.

CVS HEALTH CORPORATION, a Rhode Island Corporation, CVS PHARMACY INC., a Rhode Island Corporation, GARFIELD BEACH CVS, LLC, a California Corporation, and CVS RX SERVICES, INC., a New York Corporation, DOES 1 through 25, inclusive,

Defendants.

Case No. 4:18-cv-06271-PJH

DISCOVERY MATTER

[Assigned to Hon. Laurel Beeler for Discovery Matters]

DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFF'S MOTION TO COMPEL DISCOVERY PURSUANT TO FED. R. CIV. P. 37

DATE: **December 12, 2019**
TIME: **9:30 a.m.**
CTRM: **B – 15th Floor**
Trial Date: **February 10, 2020**

Defendants CVS Health Corporation, CVS Pharmacy Inc., Garfield Beach CVS, LLC, and CVS RX Services, Inc. (collectively, "CVS" or "Defendants") hereby submit this Memorandum of Points and Authorities in Opposition to Plaintiff Ryan Hyams' ("Plaintiff's") Motion to Compel Discovery Pursuant to Fed. R. Civ. P. 37.

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

TABLE OF CONTENTS

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

OTHER

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

I. INTRODUCTION

Plaintiff's effort to pierce the federal privilege protections afforded by the Patient Safety and Quality Improvement Act, 42 U.S.C. § 299b-21 *et seq*. ("PSQIA") confirms just why those federal privilege protections are so vital to the protection of patient safety in the delivery of healthcare to our nation's citizens.

Plaintiff was terminated from his position as CVS pharmacy manager because he lied during the course of a "DUR Enhancements" safety study (the "DUR Test") designed and implemented by the retail pharmacy division of CVS Pharmacy, Inc. ("CVS Retail") for the specific purpose of improving the safety of its pharmacy dispensing practices. CVS Retail's "Drug-to-Drug Interactions" ("DDIs") dispensing protocol required Plaintiff, when presented with a prescription that raised a red flag for a potential harmful drug interaction with medications the patient was already taking, to contact either the patient or the physician to discuss the potential for drug interaction. The documents produced from CVS's Human Resources files establish that Plaintiff did neither, but instead, entered false information into the electronic prescribing record indicating that the prescription had been confirmed with the prescribing physician. (Declaration of Robin Locke Nagele ("Nagele Dec."), ¶ 12, Ex. J, CVS 000027-CVS 000028). This unsafe practice violated CVS Retail's integrity standards and led to the termination of Plaintiff, along with the other pharmacists who lied during the DUR Test. (Nagele Dec., ¶13, Ex. K, CVS 000808-000853). Plaintiff, not willing to accept the facts revealed in the documents produced from CVS's Human Resources files, argues (without any legal basis) that he has a right to comb through CVS Retail's federally privileged Patient Safety Work Product ("PSWP"), looking for something he can use to try and make out a case against CVS in this litigation.

The federal PSQIA was intended to motivate providers such as CVS to undertake patient safety analysis such as the DUR Test by providing robust privilege protections that would protect them against the downstream litigation consequences of performing safety analysis to improve care. Nowhere does the statute limit its protections to malpractice litigation, as argued by Plaintiff. While some courts disagree as to what constitutes privileged Patient Safety Work Product ("PSWP") under the PSQIA's definitional provisions, no court has ever suggested that a

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

patient safety analysis conducted by a provider within its Patient Safety Evaluation System ("PSES") in direct collaboration with its PSO does not qualify as PSWP. Moreover, information that qualifies as PSWP is privileged no matter where it resides, with whom it is shared, and for what purpose it is used within the provider entity.

II. FACTUAL BACKGROUND

A. Enterprise PSO and the CVS Retail PSES

In 2014, Enterprise Patient Safety Organization ("Enterprise PSO" or "EPSO") was certified and listed by the Agency for Healthcare Research and Quality ("AHRQ") of the Department of Health and Human Services ("HHS") as a "component" patient safety organization ("PSO") of CVS Health. A component PSO is a PSO that is owned, managed or controlled by one or more parent organizations, such as health systems like CVS Health. 42 C.F.R. § 3.20 (Definitions - Component Organization); *see* HHS, Patient Safety and Quality Improvement: Proposed Rule, 73 Fed. Reg. 8112, 8116 (Feb. 12, 2008) ("PSQIA Proposed Rule"). EPSO, like many component PSOs of provider organizations, works in close collaboration with the providers within CVS Health, including CVS Retail, which has had a PSO Participation Agreement with EPSO since December, 2014, and has been regularly collecting and reporting PSWP to EPSO since 2015. (Nagele Dec., ¶ 7, Ex. E, Declaration of Ann Louise Puopolo ("Puopolo Dec."), ¶ ¶ 2-3).

CVS Retail's PSES is a protected space within which it collects and reports PSWP to EPSO and conducts its own patient safety deliberations and analysis in collaboration with EPSO. The CVS Retail PSES "exists anywhere . . . where CVS or its Affiliated Providers conduct Patient Safety Activities relating to CVS's Retail Pharmacy business." (Nagele Dec., ¶ 7, Ex. E, Puopolo Dec., Ex. B, CVS000783). This includes the electronic files of the patient safety team, which "regularly creates reports regarding patient safety matters, including . . . analyses, audits . . . presentations. . ." (*Id*. at CVS000785). Within the CVS Retail PSES "CVS Retail and the PSO . . . provide feedback to CVS Retail and CVS's Affiliated Providers . . . including appropriate reports, recommendations, and best practices . . . . Such feedback shall constitute the deliberations, analysis, aggregation, and/or comparison of such PSWP by the PSO or CVS Retail, and shall

occur in the CVS Retail Pharmacy [PSES]." (*Id*. at CVS000787).

This is specifically contemplated by the statute and regulations. The PSQIA was designed to "accelerate the development of new, voluntary, provider-driven opportunities for improvement, increase the willingness of health care providers to participate in such efforts, and, most notably, set the stage for breakthroughs in our understanding of how best to improve patient safety." PSQIA Proposed Rule, 73 Fed. Reg. at 8113. PSWP is the information generated in the course of these patient safety activities, *i.e*., information that is "collected or developed by a provider and reported to a PSO, or that is developed by a PSO when conducting defined 'patient safety activities,' or that reveals the deliberations of a provider or PSO within a patient safety evaluation system . . . . Thus, the proposed rule will enable health care providers to protect their internal deliberations and analysis of patient safety information . . . ." *Id*. (emphasis supplied).

EPSO and CVS Retail work together in a PSQIA-privileged environment on patient safety projects designed to improve safety at the CVS pharmacies. The CVS Retail PSES regularly creates reports regarding patient safety matters, including memoranda, analyses, audits, presentations, agendas and other materials compiled for discussion with the Retail and Enterprise Patient Safety committees. (Nagele Dec., ¶ 7, Ex. E, Puopolo Dec., ¶ 3). Puopolo, on behalf of EPSO, regularly participates in CVS Retail PSES Patient Safety Activities to provide the benefit of her expertise to assist and guide the PSES in improving patient safety for CVS Retail. These Patient Safety Activities are conducted within the CVS Retail PSES under the privilege protection of the PSQIA. *Id*.

B. The DUR Enhancements Safety Study ("DUR Test")

CVS Retail performed the DUR Enhancements safety study ("DUR Test") for the specific purpose of improving patient safety following a Chicago Tribune article that had exposed unsafe practices at pharmacies nationwide, including CVS. As explained by Thomas Davis, Vice President for Professional Services: "As a result of the findings in the Tribune article, we set about a course of identifying what enhancements we could make to the system that would improve and better safeguard our patients." (Nagele Dec., ¶ 6, Ex. D, Davis, D.T. 108: 11-15) (emphasis supplied). CVS Retail analyzed the results of the safety study within its PSES in conjunction with

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

EPSO. According to Brandon Conforti, former Senior Advisor of Patient Safety who led the study, "this entire study was Patient Safety Work Product that we were trying to inspect our systems to improve patient safety." (Nagele Dec., ¶ 5, Ex. C, Conforti, D.T. 196: 2-4).

Ann Louise Puopolo and Susan Cornacchio, as PSO workforce, participated in numerous meetings in which the audit results were discussed and analyzed for the purpose of improving patient safety in connection with CVS Retail's policies and systems pertaining to DUR Drug-to-Drug Interaction ("DDI") alerts. Summaries of the analysis of the DUR Test results were transmitted to EPSO and are maintained within the EPSO files. Documents reflecting the deliberations and analysis of those results conducted to improve patient safety, as well as communications within CVS Retail pertaining to those analyses and deliberations, are treated as privileged PSWP. (Nagele Dec., ¶ 7, Ex. E, Puopolo Dec., ¶ 5; Declaration of Susan Cornacchio ("Cornacchio Dec."), ¶ 2). Puopolo and Cornacchio have confirmed that they participated in numerous meetings in which the audit results were discussed and analyzed for the purpose of improving patient safety, and that summaries of the DUR Test results were forwarded to EPSO and maintained in EPSO's files. *Id.*[1] Brandon Conforti confirmed at his deposition that the patient safety team debriefed EPSO workforce members, Puopolo and Cornacchio, on the results of the DUR Test on a regular basis - "at least every other week." (Nagele Dec., ¶ 5, Ex. C, Conforti, D.T. 203:8-16).

C. <u>Description of the Privilege Log Documents</u>

The PSWP documents described in the Privilege Log in this case are documents that relate, specifically, to analysis of DUR Test results conducted within the CVS Retail PSES in consultation with EPSO. (Nagele Dec., ¶ 2, Ex. A).

As described, the Privilege Log documents fall into three categories:

1. Excel spreadsheets tracking and analyzing representative patient audit drug-to-drug scenarios and outcomes prepared by members of the CVS Retail patient safety

[1] Notably, the CVS Retail PSES Summary specifies that "if a part of a report or document that is PSWP is reported to a PSO, all of the PSWP collected or developed in the preparation of the reported PSWP is considered to be reported to the PSO as well." (Nagele Dec., ¶ 7, Ex. E, Puopolo Dec., ¶ 2, Ex. B, PSES Summary, § VII, p. 5 (CVS000786)).

team (Conforti and Swati Patel, Director, Retail Pharmacy Professional Practice). (Privilege Log descriptions: CVS000521–CVS000536 and CVS000704).

2. PowerPoint slide decks analyzing results of the DUR Test, including drug-to-drug interactions (with slight variations as to the specific subject of the analysis included), prepared by members of the CVS Retail patient safety team (Conforti, Davis, Stephen L. Vaudry, R. Ph. Director, Patient Safety-Retail Pharmacy). (Privilege Log descriptions: CVS000526-CVS000534, CVS000537-CVS000546, CVS000547-CVS000563, CVS000564-CVS000585, CVS000586-CVS000622, CVS000623-CVS000666, CVS000666-CVS000703).

3. Email correspondence between and among various members of the CVS Retail PSES patient safety team (Conforti, Davis, Patel, Vaudry, Erica Blanchard, PharmD, MBA, Advisor, Patient Safety-Retail Pharmacy), EPSO (Puopolo), and other CVS Pharmacy executives, discussing and analyzing various aspects of the DUR Test results and related patient safety issues, including failed audits, analyzing future potential audits and categories to monitor, addressing identified patient safety issues (including integrity issues that create safety concerns), ongoing patient safety programs, patient safety update, and DUR performance improvement. (Privilege Log Descriptions: CVS000705-760).

It is clear from the Privilege Log descriptions that the DUR Test results were shared and discussed with Puopolo. CVS000712 and CVS000714 are both copies of emails sent to Puopolo "discussing and analyzing strategic planning for addressing patient safety concerns identified during the DUR Audit." CVS000715 is a copy of an email sent to Puopolo "discussing and analyzing planned July and August 2017 DUR Audits." CVS000716 is a copy of an email sent to Puopolo "discussing and analyzing patient safety issues to identify during planned July and August 2017 DUR Audits." CVS000733 is a copy of an email to Puopolo "discussing and analyzing planned patient safety audits." These descriptions reflect that EPSO was actively involved and engaged in the deliberative process taking place in the CVS Retail PSES regarding the DUR Test, and that copies of the analysis were provided to Puopolo. Cornacchio has also confirmed that PowerPoint slides containing the DUR Test analysis were reported to EPSO on multiple occasions, including in June, September and December of 2017, for review by the EPSO workforce members in advance of meetings scheduled with the CVS Retail PSES patient safety team to discuss those results. (Cornacchio Dec., ¶ 2).

Copies of PSWP were also shared with others within CVS Retail, including Douglas Phillips, Vice President for Legal Services (CVS000727-728, CVS000744 and CVS000748), other internal legal counsel (CVS000744, CVS000748), several Human Resources executives

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

(CVS000720, CVS000729, CVS000744, CVS000748, CVS000749, CVS000752), and other operational personnel, discussing and analyzing various aspects of the DUR Test results and related patient safety issues, including failed audits, analyzing future potential audits and categories to monitor, and addressing identified patient safety issues (including integrity issues that create safety concerns), ongoing patient safety programs, patient safety updates, and DUR performance improvement. (Nagele Dec., ¶ 2.c). Internal sharing of PSWP for patient safety reasons is specifically authorized and contemplated by the PSQIA and does not diminish or waive the privilege protections.

D. CVS' Timely Invocation of the PSQIA Privilege

Defendants' Initial and Supplemental Disclosures reserved Defendants' right to not produce documents on grounds that such documents are privileged and confidential PSQIA. (Declaration of Andrew K. Haeffele ("Haeffele Dec.), ¶ ¶ 2-3, Ex. A and B). In their responses to Plaintiff's Interrogatories (Set One) and Requests for Production of Documents (Set One), served on June 28, 2019, Defendants objected to several requests on the basis of the PSQIA privilege. (Haeffele Dec., ¶ ¶ 4-5, Ex. C and D). In subsequent responses and supplemental responses to Plaintiff's discovery requests, Defendants again objected on the basis of the PSQIA privilege. (Haeffele Dec., 6-9, Ex. E-H). On August 22, 2019, Defendants served a twenty-seven (27) page privilege log in compliance with Section III(3) of Judge Laurel Beeler's Standing Order. (Haeffele Dec., ¶ 10, Ex. I).

On September 6, 2019, Defendants asked PSQIA counsel, Robin Nagele, Esq., to participate in a meet-and-confer conference call with Plaintiff's counsel for the purpose of providing a more detailed explanation of the PSQIA privilege and its application to this litigation. (Haeffele Dec., ¶ 11). Ms. Nagele complied with the request. (Haeffele Dec., ¶12, Ex. J).

III. LEGAL ARGUMENT

A. Legal Standard

The party claiming the benefits of a privilege has the burden of establishing all of the elements of the privilege. *In re Grand Jury Investigation*, 974 F.2d 1068, 1070-1071 (9th Cir. 1992). Contrary to Plaintiff's assertion, there is no "case-by-case" analysis required to determine

whether a federal statutory privilege applies. The "case-by-case" analysis is required only when a federal court is considering whether to recognize a new federal common law privilege. *See K.D. v. United States*, 715 F. Supp. 2d 587, 591 (D. Del. 2010). Rather, courts must construe and apply statutory privileges according to their plain meaning, giving full effect to congressional intent. *See Tinal v. Norton Healthcare, Inc.*, No. 3:11-cv-596-S, 2014 U.S. Dist. LEXIS 191995, *21-27 (W.D. Ky. July 15, 2014).

B. The Statutory Privilege Protections Are Comprehensive and Preemptive

The federal PSQIA is the "cornerstone of a congressional scheme, overseen by HHS, of conglomerating and analyzing data identified as [PSWP] to improve healthcare generally and nationwide." *Univ. of Ky. v. Bunnell*, 532 S.W.3d 658, 665 (Ky. App. 2017). It is designed to "move beyond the existing culture of blame and punishment that suppresses information about health care errors to a 'culture of safety' that focuses on information sharing, improved patient safety and quality and the prevention of future medical errors." S. Rep. No. 108-196, at 3 (2003).

To that end, the PSQIA "created a voluntary, non-punitive system of data sharing of healthcare errors for the purpose of improving the quality of medical care and patient safety. It envisioned that each participating provider or member would establish a [PSES] in which relevant information would be collected, managed and analyzed" and ultimately provided to its PSO. *Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital v. Azar*, No. 8:18-cv-238-T-30CPT, ECF 69, at 3 (M.D. Fla. Sept. 5, 2019) (Nagele Dec., ¶ 10, Ex. H) (emphasis supplied). "In order to encourage participation, a protected legal environment was created in which providers would be comfortable sharing data both within and across state lines 'without the threat of information being used against [them].'" *Id.* at 4, citing HHS, Patient Safety and Quality Improvement: Final Rule, 73 Fed. Reg. 70732 (Nov. 21, 2008) ("PSQIA Final Rule"). The privilege protections are "the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events." *Id.*, citing PSQIA Final Rule, 73 Fed. Reg. at 70741.

The PSQIA preempts all contrary federal or state law provisions. The PSQIA states, in relevant part, that "[n]otwithstanding any other provision of Federal, State or local law . . .[PSWP]

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

shall be privileged and shall not be: (1) subject to a Federal . . . order . . . against a provider; (2) subject to discovery in connection with a Federal . . . civil. . .proceeding . . .[or] (4) admitted as evidence in any Federal . . .proceeding . . . ." 42 U.S.C. § 299b-22(a) (emphasis supplied). *See Univ. of Ky.*, 532 S.W. 3d at 665. The express language of the PSQIA "demonstrates Congressional intent to preempt [state law] to the extent [the state law] fails to protect information qualifying as [PSWP]." *Quimbey v. Cmty. Health Sys. Prof'l Servs. Corp.*, 222 F. Supp. 3d 1038, 1043 (D.N.M. 2016). "[T]he statute speaks in plain, unequivocal terms that encompass all federal, state, or local civil or criminal proceedings." *Tinal*, 2014 U.S. Dist. LEXIS 191995, at *24.

The preemptive force of the PSQIA is not, as Plaintiff suggests, limited only to medical malpractice actions. The statute by its express terms is subject to only two narrow exceptions. PSWP may be disclosed in a criminal proceeding, but only after a court's *in camera* determination that the PSWP (i) contains evidence of a criminal act, (ii) that it is material to the proceeding, and (iii) that it cannot reasonably be obtained from any other source. 42 U.S.C. § 299b-22(c)(1)(A); 42 C.F.R. § 3.206(b)(1). PSWP may also be disclosed in an equitable proceeding brought by an individual who claims he or she sustained adverse action based upon that individual's good faith reporting of a safety incident to a PSO, or to a provider with the intention that the information be communicated to a PSO. 42 U.S.C. § 299b-22(c)(1)(B); 42 C.F.R. § 3.206(b)(2). Neither of those exceptions applies to this case. The privilege has been recognized and applied in employment discrimination cases such as this one, *see Taylor v. Hy-Vee, Inc.*, No. 15-9718-JTM, 2016 U.S. Dist. LEXIS 177764 (D. Kan. Dec. 22, 2016) and to regulatory enforcement actions, *see Ill. Dep't of Fin. and Prof'l Regulation v. Walgreen Co.*, 970 N.E.2d 552 (Ill. App. 2012). This employment action falls within the scope of the preemptive privilege protections.

C. <u>CVS Retail's "Deliberations and Analysis" are PSWP</u>

The Privilege Log documents, which reflect CVS Retail's "deliberations and analysis" of patient safety data collected and analyzed within the CVS Retail PSES in collaboration with its PSO, are quintessential PSWP. A provider's PSES is the space within which the provider conducts its own quality and safety activities. *Rumsey v. Guthrie Medical Group*, No. 4:18-cv-01605 (M.D. Pa. Sept. 26, 2019) (Nagele Dec., ¶ 8, Ex. F). The PSQIA, for instance, protects the

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

minutes of a provider's "quality meetings [which] are a core aspect of [a provider's] patient safety evaluation system." *Id*. at 6. Thus, "[a]gendas, notes, and other written records from these meetings are squarely work product and are 'deliberations and analysis of' a patient safety evaluation system." *Id*. In this case, CVS undertook, within the CVS Retail PSES, a voluntary safety study to determine the efficacy of certain enhancements that it had made to its dispensing software and policies to address patient safety issues identified in the Chicago tribune article. The Bill Summary quoted by Plaintiff (Memorandum, at 13) confirms that CVS Retail's DUR Test is exactly the type of activity that the law was intended to promote through its privilege protection:

> The bill is intended to encourage the reporting and analysis of medical errors and health care systems by providing peer review protection of information reported to patient safety organizations for the purpose of quality improvement and patient safety. These protections will facilitate an environment in which health care providers are able to discuss errors openly and learn from them. These protections apply to certain categories of documents and communications termed "patient safety work product" that are developed in connection with newly created patient safety organizations.

H.Rep. No. 109-197, at 9 (2005) (emphasis supplied).

As defined in the PSQIA and regulations, PSWP consists of data, reports, records, memoranda, analysis and written or oral statements, that: (i) are assembled or developed by a provider for reporting to a PSO and reported to the PSO; (ii) are developed by a PSO for the conduct of patient safety activities; and/or (iii) identify or constitute the deliberations or analysis of (or identifies the fact of reporting pursuant to) a PSES. 42 U.S.C. § 299b-21(7)(A). Plaintiff, advocating for an artificially narrow view of the privilege, focuses on cases and guidance discussing only the first category of information, *i.e*., information collected for reporting and reported to a PSO, but ignores the very important third category – the deliberations and analysis that occurs within a provider's PSES.

To determine whether the privilege applies to a particular provider's deliberations and analysis, the primary question is whether a PSES was in existence at the time that the deliberation and analysis occurred. PSQIA Proposed Rule, 73 Fed. Reg. at 8122. A PSES exists and the deliberations are protected so long as the provider: (i) has a contract in place with a PSO; (ii) has

the capacity to report to a PSO; (iii) has reported information to a PSO; ***or*** (iv) has actually reported the underlying information that was the basis of the deliberations or analysis to a PSO. *Id*. In this case, CVS Retail has had a contract with EPSO since 2014. It has the capacity to report PSWP and has reported PSWP to its PSOs. It has conducted patient safety analysis and deliberations within its PSES -- including, specifically, the analysis of the results of its DUR Test, which was done within its PSES in conjunction with its PSO precisely as the federal statute contemplated.

D. Plaintiff's Overly Restrictive Interpretation of the PSQIA Is Based on a Misreading of the PSQIA

Plaintiff argues that the PSQIA does not protect information that exists separately from a provider's PSES, citing 42 U.S.C. § 299b-21(7)(B)(ii), but misconstrues that provision as excluding every document not found within a provider's "reporting pathway" to a PSO. If that were true, there would be no protection at all for a provider's own "deliberations and analysis" which is expressly privileged under 42 U.S.C. § 299b-21(7)(A).

1. The Privilege Protection Is Not Limited to the Reporting Pathway

Plaintiff misleadingly argues that HHS, in 2016, stated that only information collected for reporting and actually reported to a PSO is entitled to PSQIA protection – but that is a misreading of the PSQIA and of the HHS guidance. HHS, in a document entitled "Patient Safety and Quality Improvement Act of 2005 – HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations," 81 Fed. Reg. 32655 (May 24, 2016) ("HHS Guidance"), addressed a specific issue, which was how providers could collect and report information to PSOs under the "reporting pathway" and also meet their regulatory obligations under applicable federal or state law. HHS expressly limited its discussion to the "reporting pathway" – which is only one source of protection for provider PSWP – the other being the "deliberations and analysis" pathway. *See* HHS Guidance, 81 Fed. Reg. at 32656 (noting that the privilege protection for information that is "prepared by a provider for reporting to a PSO and . . . reported to the PSO" is referred to as the "reporting pathway"); *Daley v. Teruel*, 107 N.E.3d 1028, 1037 (Ill. App. 2018) (noting that the "reporting pathway" is just one of three distinct ways that information is

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

privileged under the PSQIA). The narrow HHS Guidance document thus has no bearing on the extent of the privilege protection for a provider's "deliberations and analysis."

Likewise, *Charles v. Southern Baptist Hospital of Florida, Inc*., 209 So. 3d 1199, 1211 (Fla. 2017), which cited and relied on the HHS Guidance, was a case decided under the "reporting pathway." Specifically, in that case, the court ruled that hospital incident reports collected or maintained for reporting to a hospital's PSO could not qualify as PSWP to the extent that state law mandated that they be collected and/or maintained, and that the PSQIA did not preempt a Florida constitutional amendment (Amendment No. 7) that required hospitals to produce copies of their incident reports to patients and their attorneys. *Id*. at 1216. *Charles* is inapplicable because this case does not involved the reporting pathway, nor was CVS required under any applicable federal or state law to conduct the DUR Test – it was a voluntary study undertaken to improve patient safety.

Notably, HHS itself has strongly criticized the *Charles* decision. In a Statement of Interest filed on February 1, 2019 (Filing #84303769) in the case of *Brawley v. Smith*, No. 17-CA-000119 (Fla. Cir. Ct., 13th Jud. Cir.), a pending Florida state court case in which a patient, in reliance on *Charles*, has sought to compel a hospital to produce incident reports that the hospital has designated as PSWP, HHS stated as follows:

> In [*Charles*], the Florida Supreme Court concluded incorrectly that mandatory state disclosure laws were not preempted by the Federal Act. 209 So. 3d 1199, 1212 (Fla. 2017). [*Charles*] turns the Supremacy Clause on its head by allowing general Florida document disclosure laws to nullify the federal privilege and confidentiality protections for PSWP. States may not eliminate the privilege and confidentiality protections in the Federal Act – and gut the federal program designed to improve health outcomes through voluntary remediation of preventable errors – by foisting state disclosure requirements on providers. The potential programmatic impact is significant because [*Charles*] has no limiting principle. The scope of records covered by Amendment 7 is unbounded and could require the wholesale production of PSWP in litigation across Florida.

(Nagele Dec., ¶ 9, Ex. G) (emphasis supplied). *See also Tampa General v. Azar*, *supra* (Nagele Dec., ¶ 10, Ex. H at 5) (holding that PSQIA preempts Florida's Amendment 7).

The privilege protection for a provider's own "deliberations and analysis" is an essential

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

component of the privilege that exists separately from the "reporting pathway" privilege. Without it, the PSQIA privilege framework would be meaningless because a provider would have no protected way of working with a PSO to determine how to improve the safety of the services it provides. That would be a major deterrent to making safety improvements. If the only privilege protection that a provider was afforded under the PSQIA was a privilege to collect and report information to a PSO, and the PSQIA failed to protect the provider's own patient safety analysis and deliberations, then there would be no way for providers and PSOs to close the loop on what specific measures need to be implemented to improve patient safety at the provider level. Collecting and reporting patient safety information is not the ultimate goal of the statute – the goal is to improve patient safety. Without privilege protections for a provider's own patient safety analysis and deliberations, that goal could be put out of reach.

2. None of the Narrowing Principles of the PSWP Definition Apply

The PSQIA's definition of PSWP is limited by other exceptions that simply do not apply to this voluntary safety study. First, the PSQIA "clarifies" that PSWP does not include a patient's medical record, billing information, or other original records. 42 U.S.C. § 299b-21(7)(B)(i). CVS is not claiming privilege with respect to medical record or billing information, so that provision is not applicable.

Second, the PSQIA specifies that it shall not be construed to limit a provider's requirement to report information to governmental agencies for public health, surveillance or oversight purposes, or a provider's recordkeeping obligations under applicable law. 42 U.S.C. § 299b-21(7)(B)(iii)(II) and (III).[2] CVS Retail is under no regulatory obligation to either externally report the results of its DUR Test or to create or maintain records regarding that safety study under any federal, state or local law. Rather, the DUR Test was a purely voluntary undertaking by CVS Retail for the express purpose of improving the safety of its pharmacy dispensing system. "When there is no indication that a health care provider has failed to comply with its external record-

[2] That provision of the PSQIA also clarifies that it shall not be construed to limit the discoverability or admissibility of *non*-PSWP in a criminal, civil or administrative proceeding. 42 U.S.C. § 299b-21(7)(B)(iii)(I). That provision has no bearing on the privilege for PSWP.

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

keeping or reporting requirements and it creates supplementary information for purpose of working with a patient safety organization to improve patient safety and the quality of health care, that provider is furthering the Patient Safety Act's objectives . . . ." *Daley*, 107 N.E.3d at 1044 (emphasis supplied).

Plaintiff also places unwarranted reliance on cases where there was either no PSO relationship at all, or no evidence of active engagement between the provider and the PSO. *See e.g.*, *Dunn v. Dunn*, 163 F. Supp. 3d 1196, 1202 (M.D. Ala. 2016) (no contention that the provider was working with a PSO or that the PSQIA even applied – the provider was asking the court to recognize a non-statutory, common law privilege); *Johnson v. Cook Cnty.*, No. 15-C-741, 2015 U.S. Dist. LEXIS 115868 at *24 (N.D. Ill. Aug. 31, 2015) (no evidence that a PSO was actually receiving information from the provider or that it was providing "direct feedback and assistance to [the provider] to effectively minimize patient risk"). Plaintiff's reliance on *Quimbey v. Community Health Systems Professional Services Corp.*, No. 14-0559 KG/KBM, 2017 U.S. Dist. LEXIS 193823, at *14-15 (D.N.M. Nov. 22, 2017) is likewise misplaced. In that case, the hospital had claimed privilege under both the PSQIA and the applicable state peer review privilege for certain documents, but the affidavit submitted in support thereof had described the documents as having been produced "exclusively to carry out peer review purposes and for no other reason," *id*. at *14 (emphasis supplied) – thus creating no factual basis for arguing that they qualified for PSQIA protection. The PSWP here, by contrast, was created in direct consultation with, and reported to, the PSO.

3. Embedded Video Surveillance Does Not Make PSWP Discoverable

Plaintiff argues that CVS Retail's PSWP cannot be privileged to the extent that it contains surveillance footage/stills of pharmacists collected from store cameras. (Plaintiff's Memorandum at 5).[3] However, the PSQIA does not authorize the disclosure of PSWP merely because it contains

[3] CVS acknowledges that there is video surveillance footage of Plaintiff Hyams embedded into certain of the PowerPoint slide decks that are PSWP. (Nagele Dec., ¶ 3).

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

factual information gathered in the course of creating the patient safety analysis. In *Daley v. Teruel*, *supra*, the plaintiff sought documents related to the hospital's investigation of a safety event involving the plaintiff. The court described that information as: "an amalgamation of data, reports, discussions and reflections, the very type of information that is, by definition, patient safety work product." *Daley*, 107 N.E. 3d at 1040. The court specifically rejected the plaintiff's argument that he should be entitled discovery of facts regarding his medical treatment that were elicited as part of the hospital's patient safety investigation. *Id*. at 1041. The court noted that the investigative materials were distinct from the medical record. *Id*. In this case, the fact that video surveillance information was gathered and made a part of CVS Retail's safety analysis does not make that video discoverable. To the contrary, it is part of the patient safety analysis that the statute protects.

4. The Fact that that PSWP was Used for Internal Purposes Does Not Make it Discoverable

In addition to the core PSWP analysis, contained in the Excel spreadsheets and PowerPoint slide decks, the PSWP also consists of emails between the safety team and others within CVS Retail, including the HR department and legal counsel, transmitting and/or discussing the analysis and recommended actions. PSWP may be shared with anyone internal to CVS for patient safety purposes without violating the PSQIA or altering its status as PSWP. 42 C.F.R. § 3.206(b)(4); 42 C.F.R. § 3.208. PSWP may also be disclosed to counsel for operational reasons without altering its status or violating the PSQIA. 42 C.F.R. § 3.206(b)(9); 42 C.F.R. § 3.208. This type of internal discussion of the patient safety analysis is contemplated by the PSQIA and does not either make it separate from the PSES itself nor does it result in a waiver of the privilege.

The commentary to the PSQIA Final Rule emphasizes that "the rule does not regulate uses of PSWP within a single legal entity." PSQIA Final Rule, 73 Fed. Reg. at 70778. "[P]roviders within a single legal entity are free to discuss and share [PSWP] in identifiable and non-anonymized form for educational, academic, or other professional purposes." *Id*. In *Taylor v. Hy-Vee*, No. 15-9718-JTM, 2016 U.S. Dist. LEXIS 177764 (D. Kan. Dec. 22, 2016), the United States District Court for the District of Kansas held that, where a pharmacy had reported

medication error information to its PSO, that information constituted PSWP no matter where and how it was maintained by the provider – whether contained in medication error forms, a pharmacy logbook kept in compliance with Kansas state law, or entered into the pharmacy's internal record-keeping website, "Hy-Vee Connect." *Id.* at *6-7. The court explained: "what a pharmacy ultimately does with data collected and reported to a PSO is not relevant. Such data is designated "patient safety work product" [citation omitted], and there is nothing in the PSQIA to suggest that data can lose its designation." *Id.* at *8-9 (emphasis supplied).

HHS's commentary also makes explicit that PSWP may be used for disciplinary purposes as it was in this case – unless the discipline was imposed in retaliation for reporting a patient safety incident to a PSO:

> *Comment:* One commenter asked if permissible disclosures of [PSWP] for patient safety activities . . . could include disclosures for credentialing, disciplinary and peer review purposes.
>
> *Response*: The disclosure permission at § 3.206(b)(4) of the final rule for patient safety activities does not encompass the disclosure of [PSWP] to an external entity or within an administrative proceeding for credentialing, disciplinary, or peer review purposes. However, as explained above, uses of [PSWP] within a legal entity are not regulated and thus, [PSWP] may be used within an entity for any purpose, including those described by the commenter, so long as such use does not run afoul of the statutory prohibition on a provider taking an adverse employment action against an individual based on the fact that the individual in good faith reported information either to the provider with the intention of having the information reported to a PSO or directly to a PSO.

PSQIA Final Rule, 73 Fed. Reg. at 70779 (emphasis supplied).

Moreover, PSWP that has been shared within CVS for patient safety purposes retains its privilege. *See* 42 C.F.R. § 3.206 (b)(4) (permitted disclosure) and 42 C.F.R. § 3.208 (continued protection of PSWP). Any other result would be absurd. The central goal of the PSQIA is for providers to use PSWP to improve patient safety – so if the very act of using PSWP for its intended purpose were to waive the PSQIA privilege, there would be no privilege left.

Here, the Declarations, deposition testimony and Privilege Log establish that the CVS Retail PSES has been actively engaged with EPSO, that it in fact shared its analysis of the DUR

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

Test results with EPSO, and that EPSO was providing feedback regarding the analysis to improve patient safety. (Nagele Dec., ¶ 2, Ex. A, ¶ 7, Ex. E, Puopolo Dec., ¶¶ 3-5; Cornacchio Dec., ¶ 2; Nagele Dec., ¶ , Ex. C, Conforti, D.T. 203:8-16). The provision of feedback to participants in a PSES to improve patient safety is among the core Patient Safety Activities that PSOs are required to perform. 42 U.S.C. § 299b-21(5)(H). The very act of providing feedback to the provider so that it can take action to improve patient safety therefore cannot defeat the privilege protection.

5. The Use of Simulation Does Not Make PSWP Discoverable

Plaintiff's argument that the analysis of the DUR Test results cannot be PSWP because it did not involve real patients is a red herring. PSOs often use simulation in a PSQIA-protected environment as part of their core patient safety activities. *See, e.g.*, *https://www.teamhealth.com/blog/national-patient-safety-week* (describing a "national simulation program" as one of the Team Health PSO's featured activities for National Patient Safety Week). CVS designed the study specifically so that it could evaluate its safety protocols in a real world setting, involving actual licensed pharmacies and pharmacists, but in a manner that would avoid patient harm. It would be strange indeed if the PSQIA were interpreted to require CVS to choose between privilege protection and an unsafe study design that could potentially harm patients. Plaintiff provides no authority to support his assertion that the PSQIA was not intended to protect an analysis based on simulated patient interactions.

E. <u>CVS Has Not Waived the PSWP Privilege</u>

The PSQIA privilege has not been, nor could it be, waived. Neither CVS's policies nor the Participation Agreement allow for waiver of the statutory prohibitions on disclosure in the absence of one of the narrowly drawn statutory disclosure permissions, none of which apply here. In particular, a provider's "deliberations and analysis," unlike information it has collected for reporting to the PSO, may *not* be removed from the PSES and used for other purposes. *See* 42 C.F.R. § 3.20 (Definitions – PSWP (2)(ii)) (describing circumstances under which information "<u>assembled or developed by a provider for reporting to a PSO</u>" as defined under Section (1)(i)(A) of the Definition may be removed from the PSES and no longer considered PSWP; this limited exception does not apply to "deliberations and analysis" created under Section (1)(ii)). Persons

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

who disclose PSWP in violation of the strict statutory provisions are subject to sanctions and fines for each violation. 42 U.S.C. §299b-22(f); 42 C.F.R. § 3.404(b).

Plaintiff seizes on the fact that some of the PSWP was shared with CVS's internal counsel to try and shoehorn his arguments into "reliance on counsel" or "subject matter waiver" of the attorney-client privilege. But, the issue is PSQIA privilege, not attorney-client privilege and, in any event, CVS has not asserted any reliance on counsel defense here, nor has CVS has made the content of its patient safety analysis the heart of its case. *See, e.g.*, *Kaiser Found. Health Plan v. Abbott Labs, Inc*., 552 F.3d 1033, 1043 (9th Cir. 2009) (rejecting plaintiff's argument that advice-of-counsel defense waived attorney-client privilege because the defendants did not assert they relied on the advice counsel had given).

Plaintiff misconstrues *Bittaker v. Woodford*, 331 F.3d 715, 720 (9th Cir. 2003) as suggesting a broad subject matter waiver doctrine extending beyond the confines of the attorney-client privilege when, in fact, what the court fashioned was a very "closely tailored" waiver tied to the ineffective assistance of counsel claim being pursued by the *habeas corpus* petitioner. CVS has not asserted any defense that turns on the content of privileged PSWP. If, as Plaintiff would like to suggest, the assertion of a defense in litigation were construed as a waiver of any privilege as to any information that might potentially be relevant or helpful, then this would eviscerate the very notion of privilege protection. *FTC v. Qualcomm Inc*., No. 17-cv-00220-LHK, 2018 U.S. Dist. LEXIS 208192, at *12 (N.D. Cal. Dec. 10, 2018), citing *Cervantes v. CEMEX, Inc*., No. 1:12-cv-1932-LJO-JLT, 2014 U.S. Dist. LEXIS 115652 at *20, n. 1 (E.D. Cal. Aug. 18, 2014) ("if this mere showing . . . was deemed sufficient, the privilege would be completely eviscerated.").

F. Plaintiff Has Ignored CVS's Offer To Produce the PSWP that Plaintiff Claims He Needs To Litigate This Case

Plaintiff would like this court to believe that CVS is hiding behind the PSWP privilege to withhold relevant information, but fails to acknowledge that CVS actually offered to produce those portions of the PSWP that identify Hyams and CVS Retail (and no other providers) pursuant to an exception to the strict confidentiality requirements that permits disclosure of PSWP if

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

authorized by all identified providers. Plaintiff has ignored this offer.

The PSQIA specifies that identifiable PSWP may be disclosed "if authorized by each provider identified in such [PSWP]." 42 U.S.C. § 299b-22(c)(1)(C). The regulations set forth the requirements for a valid authorization pursuant to this provision. It must:

> (A) Be in writing and signed by the provider from whom authorization is sought;
>
> (B) Contain sufficient detail to fairly inform the provider of the nature and scope of the disclosures being authorized.

42 C.F.R. § 3.206(B)(3)(i)(A)-(B). The disclosing entity must obtain a valid authorization from each provider identified in the PSWP, and must maintain the authorization on file for a period of six years from the last disclosure made pursuant to that authorization. 42 C.F.R. § 3.206(b)(3). Moreover, PSWP disclosed pursuant to this type of authorization retains its character as privileged PSWP for all purposes other than those that have been authorized. 42 C.F.R. § 208.

On October 11, 2019 CVS, through counsel, offered to produce all documents that relate directly to Plaintiff Hyams (and redacted as to all other identified providers except Hyams and CVS) pursuant to a 42 C.F.R. § 3.206(b)(3) authorization. (Nagele Dec., ¶ 4, Ex. B). This would have provided Plaintiff with precisely the information that he claims CVS is improperly withholding – *i.e.*, CVS Retail PSES deliberations and analysis relating to Plaintiff's conduct in connection with the DUR Test. However, Plaintiff ignored that offer, and instead continues to argue to this Court that CVS is attempting to avoid producing information he deems relevant to his case.

G. *In Camera* Inspection Is Not Warranted

Plaintiff has not provided a sufficient basis for *in camera* inspection of the PSWP, *i.e.*, a reasonable, good faith belief that the documents are not privileged. *In re U.S. Grand Jury Investigation*, 974 F.2d 1068 (9th Cir. 1992) (government failed to establish a sufficient factual basis for *in camera* inspection of privileged documents by the district court). The basis and context of the Hyams termination is established by his disciplinary records. For comparative purposes, CVS has produced the corrective action records for pharmacists receiving termination and lesser discipline as a result of the DUR Test. These records explain the basis of the

disciplinary action taken. There is no reasoned basis for Plaintiff to seek access to the federally privileged patient safety analysis identified on the Privilege Log and maintained within the CVS Retail PSES.

III. CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Compel production of the documents identified as PSWP in Defendants' Privilege Log should be denied.

DATED: November 14, 2019

PAYNE & FEARS, LLP

BY: /s/ *Andrew K. Haeffele*
DANIEL F. FEARS
LEILA NARVID
ANDREW K. HAEFFELE

POST & SCHELL, P.C.

BY: /s/ *Robin Locke Nagele*
ROBIN LOCKE NAGELE
1600 J.F.K. Boulevard, 13th Floor
Philadelphia, PA 19103
215-587-1000
Pro Hac Vice

Attorneys for Defendants CVS Health Corporation; CVS Pharmacy, Inc.; Garfield Beach CVS, LLC; CVS RX Services, Inc.

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850

CERTIFICATE OF SERVICE

I hereby certify that on this date, a true and correct copy of the foregoing Defendants' Memorandum of Points and Authorities in Opposition to Plaintiff's Motion to Compel Discovery Pursuant to Fed. R. Civ. P. 37 was electronically filed with the Court in the above matter and therefore has been served upon the following counsel of record, electronically:

Beth A. Gunn, Esq.
Catherine J. Coble, Esq.
David Z. Feingold, Esq.
Gunn Coble LLP
101 S. 1st Street, Suite 407
Burbank, CA 91502
Telephone: (818) 900-0695
Fax: (818) 900-0723
beth@gunncoble.com
cathy@gunncoble.com
dfeingold@gunncoble.com

DATED: November 14, 2019 PAYNE & FEARS, LLP

BY: /s/ *Andrew K. Haeffele*
DANIEL F. FEARS
LEILA NARVID
ANDREW K. HAEFFELE

PAYNE & FEARS LLP
ATTORNEYS AT LAW
235 PINE STREET, SUITE 1175
SAN FRANCISCO, CALIFORNIA 941044
(415) 738-6850